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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/393,441	09/08/99	ANDERSON C	660088.420C1

000500 HM22/1122
SEED INTELLECTUAL PROPERTY LAW GROUP PLL
701 FIFTH AVE
SUITE 6300
SEATTLE WA 98104-7092

EXAMINER	
SCHNIZER,H	
ART UNIT	**PAPER NUMBER**
1653	6

DATE MAILED: 11/22/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

FILE COPY

Office Action Summary	Application No. 09/393,441	Applicant(s) And rson t al.
	Examiner Holly Schnizer	Group Art Unit 1653

☒ Responsive to communication(s) filed on *Nov 29, 1999*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-112* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-112* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 6 and 27, drawn to recombinant expression constructs encoding an ANT1 polypeptide, classified in class 435, subclass 320.1.

II. Claims 7 and 28, drawn to recombinant expression constructs encoding an ANT2 polypeptide, classified in class 435, subclass 320.1.

III. Claims 8 and 29, drawn to recombinant expression constructs encoding an ANT3 polypeptide, classified in class 435, subclass 320.1.

Claims 1-4, 8, 9-26, and 30-41 link Groups I-III. These linking Claims will be examined with respect to the subject matter of the Invention of Groups I, II, or III, if one of these Groups is elected.

IV. Claim 44, drawn to ANT1 polypeptide, classified in class 530, subclass 300.

V. Claim 45, drawn to ANT2 polypeptide, classified in class 530, subclass 300.

VI. Claim 46, drawn to ANT3 polypeptide, classified in class 530, subclass 300.

Claims 42, 43, 47, and 48-57 link Groups IV-VI. These linking Claims will be examined with respect to the subject matter of the Invention of Groups IV, V, or VI, if one of these Groups is elected.

VII. Claim 60, drawn to a method of determining the presence of an ANT1 polypeptide in a sample, classified in class 435, subclass 7.1 .

VIII. Claim 61, drawn to a method of determining the presence of an ANT2 polypeptide in a sample, classified in class 435, subclass 7.1 .

IX. Claim 62, drawn to a method of determining the presence of an ANT2 polypeptide in a sample, classified in class 435, subclass 7.1 .

Claims 58-59, 63-71, and 72-74 link Groups VII-IX. These linking Claims will be examined with respect to the subject matter of the Invention of Groups VII-IX, if one of these Groups is elected.

X. Claims 75-84 and 104 drawn to a method for identifying an agent that binds to an ANT polypeptide and an assay plate for high throughput screening of candidate agents that bind ANT polypeptide, classified in class 435, subclass 7.1.

XI. Claims 85-103 and 107-111, drawn to an ANT ligand, classified in class 530, subclass 300.

VII. Claims 105-106 drawn to a method of targeting a polypeptide to the mitochondrial membrane, classified in class 435, subclass 317.1.

VIII. Claim 112, drawn to a method of treatment comprising administering a pharmaceutical composition comprising an ANT ligand, classified in class 514, subclass 2.

2. The inventions are distinct, each from the other because of the following reasons:

3. The inventions of Groups I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the genes encoding ANT1, ANT2, and ANT3 are distinct and encode proteins having different structures, functions, and which are expressed in different tissues. For example, ANT1 is expressed in heart and skeletal muscle; ANT2 appears to only be expressed in neoplastically transformed cells with high glycolytic rates, in tumors, and tumoral cells; and ANT3 is ubiquitously expressed (Giraud et al. J. Mol. Biol. (1998) 281: 409-418, see p. 409, col. 2; ref. BF in IDS filed Sept. 12, 2000 as Paper No. 5). Moreover, while ANT1 and ANT3 export ATP synthesized in the mitochondria to the cytosol, ANT2 appears to translocate glycolytic ATP synthesized in the cytosol, to the mitochondrial matrix (see Giraud et al. p. 413, Col. 2). Because the ANT protein isoforms are expressed in different tissues and have different structures and functions, the polynucleotides encoding them are independent and distinct, one from the other, and could be used for different purposes and have different effects.

4. The inventions of Groups IV-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the ANT1, ANT2, and ANT3 polypeptides are distinct are unrelated for the reasons stated in the preceding paragraph. ANT1, ANT2, and ANT3 proteins having different structures, functions, and which are expressed in different tissues. Because the ANT protein isoforms are

expressed in different tissues and have different structures and functions, they are independent and distinct, one from the other, and could be used for different purposes and have different effects.

5. The inventions of Groups I-VI and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the expression constructs and host cells of Inventions I-III, the polypeptides of Inventions IV-VI, and the ligands of Invention XI have different biological structures and different functions. In addition, subject matter of each Group is not coextensive and thus the search for each would constitute a serious burden upon the examiner. For example, the expression constructs of Group I would require consideration of its use for processes other than the production of the protein, such as nucleic acid hybridization assay and the protein would required searches of literature wherein the protein was isolated from its source rather than recombinantly produced using the polynucleotide. Thus, Groups I-III require considerations which are not required in the search for proteins of Groups IV-VI and Groups IV-VI require considerations which are not required in the search for the polynucleotides of Groups I-III. Likewise, the polypeptides of Groups IV-VI have different functions and are used for different purposes than the ligands of Group XI.

6. The expression vectors of Groups I-III are unrelated to the methods of Groups VII-X and XIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects

(MPEP § 806.04, MPEP § 808.01). In the instant case, the expression vectors of Groups I-III are not made by nor used in the protein binding assays of Groups VII-X or the method of treatment using an agent that binds ANT of Group XIII.

7. Inventions I-III and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the expression vectors of Groups I-III can be used in a method of making the polypeptides or in hybridization assays which are materially different processes than the method of targeting the ANT polypeptide to the mitochondrial membrane of Invention XII.

8. The ANT polypeptides of Groups IV-VI are unrelated to the methods of Groups VII-IX and XIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the polypeptides of Groups I-III are not made by nor used in the method of screening using an ANT ligand of Groups VII-IX or the method of treatment using an agent that binds ANT of Group XIII.

9. Inventions IV-VI are related to the methods of Groups X and XII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of

using that product (MPEP § 806.05(h)). In the instant case, the polypeptides of Groups IV-VI can be used in a method of making an antibody or in activity assays which are materially different methods than the protein binding assays and method of treatment using an ANT ligand of Groups X and XIII.

10. The ANT ligands of Group XI are unrelated to the methods of Groups X and XII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the ligands of Group XI are not made by nor used in the method of screening using an ANT polypeptide of Group X or the method of targeting an ANT polypeptide to the mitochondrial membrane of Group XII.

11. The ligand of Invention XI is related to the methods of Inventions VII-IX and XIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the ligand of Invention XI could be used in a method of inhibiting the activity of the ANT polypeptides which is materially different than the method of screening for an ANT polypeptide of Groups VII-IX or the method of treatment of Group XIII. In addition, the ligand could be used in a method of diagnosis which is materially different from the methods of screening and treatment of Inventions VII-IX and XIII.

12. The methods of Groups VII-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the ANT polypeptides are expressed in different tissues and have different structures and functions. Therefore, the different screening methods could not be used together and each method would have different endpoints since each would likely bind ligands of differing structure.

13. The methods of Inventions VII-X, XII, and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Inventions VII-X, XII, and XIII are materially different each from the other because each is practiced with materially different process steps, technical considerations, and reagents and each is practiced to accomplish a distinct goal.

14. Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP § 803). Therefore, the initial requirement of restriction for examination purposes as indicated is proper.

15. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

16. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (703) 305-3722. The examiner can normally be reached Monday and Thursday from 8:00 a.m. to 5:30 p.m. and Tuesday and Wednesday from 9:00 a.m. to 2:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 306-4119. The fax phone number for Official Papers to this Group is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen Cochrane Carlson PhD

Holly Schnizer, Ph.D.
November 20, 2000

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER